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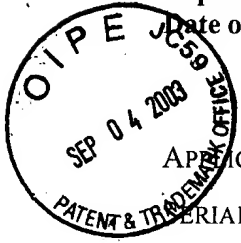
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Attorney Docket No. 15966-546 CON-S22

Date of Deposit: September 4, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



APPLICANTS: Fernandes et al.

SERIAL NUMBER: 09/966,545

EXAMINER: Regina M. DeBerry

FILING DATE: September 26, 2001

ART UNIT: 1647

FOR: NOVEL KIAA1061-LIKE CELL ADHESION MOLECULE-LIKE PROTEINS AND
POLYNUCLEOTIDES ENCODING THEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Boston, Massachusetts
September 4, 2003

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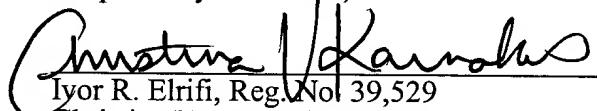
TRANSMITTAL LETTER

Transmitted herewith for filing in the present application are the following documents:

- ☒ Response and Amendment (9 pages);
- ☒ Petition for Extension of Time (1 page);
- ☒ Check No. 17036 in the amount of \$465.00 to cover the Extension Fee;
- ☒ Declaration Under 37 C.F.R. § 1.132 (15 pages); and
- ☒ Return postcard.

Please charge any additional fees that may be due, or credit any overpayment of same, to
Deposit Account No. 50-0311 (Reference No. 15966-546 CON S-22). A duplicate copy of this
Petition is enclosed.

Respectfully submitted,


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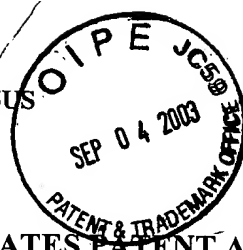
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DECLARATION UNDER 37 C.F.R. § 1.132

I, Valerie Gerlach hereby declare and state as follows:

1. I am employed by CuraGen, Inc., the assignee of this application. My title is senior research scientist. I received a Ph.D. in Cellular and Molecular Biology in 1996 from the University of Wisconsin-Madison. I was a post-doctoral fellow in the laboratory of Dr. Errol Friedberg at the University of Texas Southwestern Medical Center in Dallas, Texas from 1996 to 2000.

2. I have read, and am familiar with, the contents of the United States Patent Application entitled "Novel KIAA1061-Like Cell Adhesion Molecule-Like Proteins and Polynucleotides Encoding Them", serial number 09/966,545, which was filed September 26, 2001. I understand that the pending claims are directed to an isolated polynucleotide SEQ ID NO: 15, encoding polypeptide SEQ ID NO: 16.

3. I am aware that the Examiner has issued an Office Action. In particular, I understand that the Examiner has rejected the pending claims under 35 U.S.C. §§ 101 and 112, contending that the pending claims are not supported by either a specific and substantial asserted utility or a well-established utility.

4. I make this declaration to rebut the Examiner's assertion, with which I do not agree. It is my belief and professional scientific determination that the claimed compositions have a specific and substantial utility due to the following facts.

5. I have performed, or have had performed under my supervision, scientific studies evaluating the quantitative expression and sequence homology of the claimed nucleic acid SEQ ID NO 15, encoding the polypeptide SEQ ID NO: 16 in tissue culture cells and in isolated normal and pathological human tissues.

6. Expression of the 4324229-2(CG52643-02) gene SEQ ID NO: 15 was higher in normal kidney tissue compared to kidney tumors. Specifically, in one experiment, expression of this gene was downregulated in 6/9 kidney tumors when compared to matched normal adjacent tissue, confirmed in a second experiment which showed expression downregulated in 8/8 kidney cancer samples when compared to normal adjacent controls tissue. In contrast, expression of this gene was upregulated in 6 out of 10 lung cancer cell lines relative to normal lung; 7 out of 8 breast cancers compared to normal breast, including in two pairs of samples with tumor and matched normal adjacent tissue; in 2/2 bladder cancers and 1/2 ovarian cancer specimens. Therefore, expression of the CG52643-02 gene or protein is useful to detect and differentiate kidney, lung, breast, and ovarian cancer tissues from normal tissues.

7. The results of these studies demonstrate that the nucleic acid and the encoded claimed polypeptide of SEQ ID NO: 16 are useful at least in detection, differentiation and therefore diagnostic applications in cancer. Thus, it is my opinion and belief that the Examiner should withdraw the rejection and allow the pending claims.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this application and any patent issuing there from.

Valerie Gerlach
Valerie Gerlach

Signed at New Haven, CT
this 4TH day of September, 2003.